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| 09/834,312 | 04/13/2001 | Lisbeth Illum | 8567-603US<br>(WESR/P21598US | 2569 |

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| EXAMINER |
|---|
| FUBARA, BLESSING M |

| ART UNIT | PAPER NUMBER |
|---|---|
| 1615 | 7 |

DATE MAILED: 03/27/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

| Office Action Summary | Application No. 09/834,312 | Applicant(s) ILLUM ET AL. | |
|---|---|---|---|
| | Examiner Blessing M. Fubara | Art Unit 1615 | |

*-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --*

**Period for Reply**

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

1)☒ Responsive to communication(s) filed on *03 January 2002* .

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

4)☒ Claim(s) *1-14 and 20-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-4, 9-20 and 22* is/are rejected.

7)☒ Claim(s) *5-8 and 21* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

**Application Papers**

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

**Priority under 35 U.S.C. §§ 119 and 120**

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

**Attachment(s)**

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

## DETAILED ACTION

Examiner acknowledges receipt of paper number 6 filed 01/03/02. Claims 1-14 and 20-22 are pending in the application.

### *Claim Rejections - 35 USC § 101*

The rejection of claims 15-19 under 35 U.S.C. 101 reciting use, without setting forth any steps involved in the process is withdrawn because the said claims are cancelled by the amendment filed on 01/03/02.

### *Claim Rejections - 35 USC § 102*

1. Claims 1-4, 9-14. 20 and 22 remain rejected under 35 U.S.C. 102(b) as being anticipated by Cupps et al. (US 5,691,370).

Applicants ague that terfenadine carboxylate differs from fexofenadine and to support that position provided a structure applicant describes as terfenadine (see page 5 of the response). However, applicants' arguments filed 01/03/02 have been fully considered but they are not persuasive because fexofenadine and terfenadine carboxylate are the same as given in the registry file of STN.

Cupps discloses a pharmaceutical comprising terfenadine or terfenadine carboxylate, carriers lactose, sucrose, starches, propylene glycol, glycerin and mannitol and suspending agents such as tragacanth and sodium alginate (column 16, line 23 to column18 line 48 and claim 1). Cupps specifically teaches intranasal and intraocular dosage form and discloses that topical intraocular composition comprises poloxamer vehicles (column 18, lines 13-48). The teachings of Cupps meet the limitations of the claims.

2. Claims 1-3, 14 and 20 remain rejected under 35 U.S.C. 102(e) as being anticipated by Wong et al. (US 6,120,803).

Applicants ague that Wong's active agent in solid capsule dosage form is adapted for retention in the stomach and thus useful in prolonged delivery of an active agent formulation to a fluid environment and that the capsule is made of polymer matrix that swells upon contact with water. Applicants further state that the Wong capsule is able to withstand muscular contractions in the stomach because of the structure of the composition. Furthermore, applicants state that fexofenadine is one of the active agents in the list of active agents listed in Wong and that Wong does not teach pharmaceutical excipients that increase the solubility of fexofenadine.

Applicants' arguments filed 01/03/02 have been fully considered but they are not persuasive because applicants generic claim broadly recites a composition comprising fexofenadine of pharmaceutically acceptable salt and excipient. While the properties of the composition is not critical over the prior art the, any excipient would have the ability to increase the solubility of the fexofenadine or its salt in water because the generic claim recites excipient and it is not critical that the prior art is silent on the word pharmaceutical except applicants have evidence to the contrary that the excipient of the prior art id not pharmaceutical. The prior art only has to teach a composition comprising fexofenadine and a carrier. Fexofenadine is a pharmaceutical. Although Wong gives a list of active ingredients that a suitable in the prior art composition, Wong nonetheless teaches that fexofenadine is one of the drugs that can be present in the composition. The comprising language of the claims does not exclude other ingredients and the claims do not exclude capsule dosage forms. The property and future intended use is not critical in a composition claim.

Wong discloses a composition comprising fexofenadine, surfactants, carriers and excipients (column 5, lines 13-19, 44-49 and 56-61, column 6, lines 13-25, column 17, lines 22-38 and claims 4 and 6). The teachings of Wong meet the limitations of the claims.

3. Claims 1-3, 12-14 and 20 remain rejected under 35 U.S.C. 102(e) as being anticipated by Lech (US 6,027,746).

Applicants ague that Lech discloses a list of drugs for use in chewy capsules and fexofenadine is one of them. Applicants sate that the drug is adsorbed onto flake-like particles of an adsorbate so that the drug is prevented form dissolving into the liquid or solid excipient. Applicants further state that the excipients in Lech are sorbitol, glycerin, corn syrup, sugar, alcohols and mixtures thereof. Furthermore, applicants state that the drug is suspended in a fill material that does not increase the solubility of fexofenadine.

Applicant's arguments filed 01/03/02 have been fully considered but they are not persuasive because applicants claim a composition comprising fexofenadine and excipient. Sorbitol, glycerin, corn syrup, sugar, alcohols and mixtures that are excipients in Lech read on the scope of excipient recited in the generic claim. The prior art only has to teach the composition and the properties or future intended use is not critical in a composition claim. Disclosing fexofenadine in the lists of drug that can be used in the composition is a teaching of a composition comprising excipient and fexofenadine.

Lech discloses a pharmaceutical composition comprising fexofenadine (column 4, line 7), excipients (column 4, lines 52-56) and poloxamer 407 (column 6, lines 35-61). See also abstract and claims 1-8. The teachings of Lech meet the limitations of the claims.

4. Claims 1-4, 12-14 and 20 remain rejected under 35 U.S.C. 102(e) as being anticipated by Ahlgren et al. (US 6,117,452).

Applicants state that the composition of Ahlgren is formulated into orally ingestible tablets, pills, capsules, troches and liquid suspensions and although Ahlgren contemplates transdermal, buccal and nasal products, these dosage forms are not adapted for administration to the eye or nose. Applicants also state that Ahlgren's does not specifically teach an excipient that would increase the solubility of fexofenadine since the excipients of Ahlgren are water-insoluble.

Applicant's arguments filed 01/03/02 have been fully considered but they are not persuasive because the future intended use is not critical in a composition claim. The prior art only has to teach the composition and the excipients of Ahlgren read on the scope of the claimed excipients. The claims have not excluded tablets, pills, capsules, troches and liquid suspensions.

Ahlgren discloses a composition comprising fexofenadine, excipients and surfactants such as Poloxamers, Tweens and Spans (column 2, lines 7-65, column 6, lines 9-38, and claims 3, 4, 8, 13 and 21). Ahlgren teaches that the composition is formulated into tablets, pills, capsules, troches and liquid suspension and specifically states that transdermal, buccal and nasal dosages are contemplated (column 6, lines 28-30). The teachings of Ahlgren meet the limitations of the claims.

5. Claims 1-3, 9-11, 14, 20 and 22 remain rejected under 35 U.S.C. 102(a) as being anticipated by pages 1189 to 1190 of the 1998 physician desk reference.

Applicants ague that the composition disclosed in the PDR is a solid form and does not teach other dosage forms and the PDR composition is not adapted for administration to the eye

or nose. Applicants also state that the excipients used in the composition of the PDR do not increase the solubility of the fexofenadine.

6. Applicant's arguments filed 01/03/02 have been fully considered but they are not persuasive because the prior art only has to teach a composition comprising fexofenadine and excipients. The scope of the excipients in the PDR read on the broad excipient recited in the claims. A future intended use and the properties of a composition are not critical in a composition claim.

The 1998 physician desk reference discloses a capsule dosage form of fexofenadine (ALLEGRA™). The dosage form comprises excipients and other additives such as iron oxide, gelatin, silicon dioxide, titanium dioxide and sodium lauryl sulfate. See pages 1189-1190, 1998 PDR. This publication on ALLRGRA meets the limitations of the claims.

The claimed invention is directed to a composition comprising fexofenadine or pharmaceutically acceptable salt and a pharmaceutical excipient. Applicants claim a broad generic invention comprising fexofenadine antihistamine and an excipient. The route of administration is not critical in a composition claim and what the excipient does is not critical in a composition claim. The prior art only has to teach the composition to meet the limitations of the claims. The language of comprising does not exclude other ingredients/additives/carriers/excipients that the invention may be silent on in the claims. The method claims recite generic administration of a composition/formulation/dosage from to a patient in need thereof.

7. Claims 5-8 and 21 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

8. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

9. Applicants' cooperation is requested in correcting any errors of which applicants may become aware in the specification including the claims.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Blessing M. Fubara whose telephone number is 703-308-8374. The examiner can normally be reached on 7 a.m. to 3:30 p.m. (Monday to Friday).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Thurman K. Page can be reached on 703-308-2927. The fax phone numbers for the organization where this application or proceeding is assigned are 703-305-3592 for regular communications and 703-305-3592 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1234.

Blessing Fubara
March 22, 2002

THURMAN K. PAGE
SUPERVISORY PATENT EXAMINER
TECHNOLOGY CENTER 1600